DEPARTMENT OF HEALTH & HUMAN SERVICES M1003N Public Health Service

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

June 16, 1997

cc: HFI-35/FOI Staff
DWA

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 97-48

Paula J. Quinn
President
Heart Foods Company, Inc.
2235 East 38th Street
Minneapolis, Minnesota 55407

Dear Ms. Quinn:

This letter is in reference to your firm's marketing and distribution of "Cayenne Power Caps" and "Cayenne Heart Food Caps" that are being promoted to treat disease conditions.

Promotional material (labeling) includes "Dr. Atkins' Health Revelations" and "Health & Healing" which describe Capsaicin as follows: "particularly helpful for arthritis, heart disease, circulation disorders, and other diseases." Additional claims include, but are not limited to, "...used as a treatment for peptic ulcers" and "eases blood pressure...lowers hypertension."

These newsletters specifically refer to your firm and/or your products by name in conjunction with stated disease claims. Distribution of this promotional material with product(s) causes this literature to become labeling.

Thus, "Cayenne Power Caps" and "Cayenne Heart Food Caps" are drugs as described in Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the

Act). These products are also "new drugs" as defined in Section 201(p) of the Act and, therefore, may not be marketed in the United States without approved new drug applications under Section 505 of the Act.

These drugs are also misbranded as described in Section 502(f)(1) of the Act because the labeling fails to bear adequate directions for use and because the labeling is false and misleading under Section 502(a) of the Act as it suggests that the products are safe and effective for their intended uses when, in fact, this has not been established.

This letter is not intended to be an all-inclusive review of all labeling and products marketed by your firm. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations.

We request that you take prompt action to correct these violations. Failure to promptly correct violations may result in enforcement action being initiated by the Food and Drug Administration without further notice. The Federal Food, Drug and Cosmetic Act provides for the seizure of illegal products and for injunction against the manufacturer and/or distributor of illegal products.

Please notify this office in writing within 15 working days of receipt of this letter of the specific steps you have taken to correct the stated violations. You should also include an explanation of each step being taken to identify and make corrections to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be implemented.

Your reply should be sent to Compliance Officer Thomas P. Nelson at the address indicated on the letterhead.

Sincerely,

James I. Roberts
Acting Director
Minneapolis District

TPN/ccl